ChromaTan Receives a $2.5 Million Contract from the FDA
For the Development of a New Continuous Purification Platform
For Single-Use and Continuous Bio-manufacturing

ChromaTan Corporation, a provider of continuous and single-use chromatography solutions for the biotechnology industry, has been awarded a $2.5 Million dollar contract from the Food and Drug Administration (FDA). The project involves the development of an integrated, continuous downstream purification platform for production of monoclonal antibodies. The objective of the project is to drive significant improvements in product quality, as well as to enable more flexible manufacturing facilities and cost-of-goods reductions, for production of life-saving antibody therapies.

The two-year project will focus on process development, design, and testing of a multi-unit operation process train that can continuously purify a monoclonal antibody (mAb) harvested from a CHO cell-based bioreactor system at steady state through multiple purification modalities. The bulk of the work on the platform called CCTC™ - Continuous Countercurrent Tangential Chromatography (CCTC) - will be performed at ChromaTan’s new laboratory location in West Philadelphia.
To meet the goals of the 2-year project, ChromaTan expects to be announcing job openings in the areas of R & D management, Process Analytical Technologies (PAT) and Quality Control.

Oleg Shinkazh, ChromaTan’s founder and CEO, stated “We are thrilled to begin execution of this contract. At this time there is no doubt that continuous manufacturing is on its way to becoming a reality in bioprocessing. We believe we have a unique offering in our CCTC platform that will enable manufacturers to transform the way they produce these much-needed therapies. We also look forward to working with the experienced team at the FDA to provide feedback and guidance on the framework for regulatory compliance of the CCTC platform and for the overall field of continuous bioprocessing.”

ChromaTan, a startup at the Innovation Park bioprocessing space based in State College, PA, developed CCTC as a novel column-free purification technology. Their recent work with major biopharmaceutical companies has demonstrated that CCTC provides significant improvements over conventional batch purification solutions in terms of productivity, product quality, and ease-of-use. The company is funded by individual investors, NIH SBIR grants, Pennsylvania state funds, Ben Franklin Technology Partners of Central PA, and Life Science Greenhouse of Central PA.

ChromaTan is actively engaging with customers on R & D partnerships for beta testing the CCTC platform. The company is also preparing for an equity fundraising round. Qualified potential partners and investors may contact ChromaTan for more information at www.chromatanz.com/contact.

ChromaTan will exhibit the beta process development system with partner Purolite at the upcoming BioProcess International Conference in Boston (Sep 25 – 28) at booth 1323. They will also announce a number of job openings. Please visit ChromaTan at www.chromatanz.com.

CCTC™ is a trademark of ChromaTan Corporation.

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